6. 510(k) Summary

General Information

Date : April 16, 2013

Classification Class II, 21 CFR § 870.1340, Introducer, Catheter, Product code DYB

Trade Name Creganna-Tactx™ Steerable Sheath Set

Model Numbers 139294-01, 139294-02

Submitter Creganna-Tactx Medical
Parkmore West
Galway, Ireland

AUG 1 2013

Regulatory Contact Christine E. Nichols RAC
Boston Biomedical Associates
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Intended Use

The Creganna-Tactx Steerable Sheath Set is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Predicate Device

Agilis NxT™ Steerable Introducer K081645, K061363
Manufactured by St. Jude Medical (SJM)

Device Description

Steerable Sheath

The Creganna-Tactx Steerable Sheath is a stainless steel braided steerable sheath which is compatible with EP Catheters ≤ 8.7Fr and has an approximate working length of 720mm. It is designed to provide flexible catheter positioning in the cardiac anatomy. The handle is equipped with a bi-directional rotating knob to deflect the tip clockwise ≥ 180° and counterclockwise ≥ 90°. There are two different models: The *Symmetric* Steerable Sheath has a tip that can be deflected into two distal curve geometries of equal symmetry, with reduced stroke in one direction; and the *Asymmetric* Steerable Sheath – one distal curve equal to the symmetric curve geometry above and a longer 'reach' curve geometry on the opposite curve to facilitate broader steering angles.

The steerable sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A side-port with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. The steerable sheath features distal perfusion holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization.

Steerable Sheath Set
The Creganna-Tactx Steerable Sheath is packaged as a set with the following accessories that are compatible with the dimensions of the steerable sheath:
a polymer curved dilator (approximately 8.7 Fr), a 0.032" PTFE coated stainless steel J-tipped guidewire, and a guidewire J-straightener (introducer). The Set components are packaged together, provided sterile, and is intended for single use only.

Materials
The Creganna-Tactx Steerable Sheath Set assembly is comprised of materials that are commonly used in medical device applications.

Testing
In vitro testing was performed on the Creganna-Tactx Steerable Sheath Set to assure reliable design and performance in accordance with applicable standards, intended use and user requirements. In addition, comparative testing to the predicate device was performed to show substantial equivalence. The non-clinical tests performed by the company include:

Functional Testing
- Shaft and Tip Flexibility
- Tracking Test for Dilator and EP Catheters through Sheath
- Torque Testing
- Kink Resistance
- Articulation Tests
- Simulated Use Testing
- Hemostasis Valve Leak Test and System Leak Tests per ISO11070;
- Strength of Connections per ISO10555-1

Biocompatibility Testing
Testing per ISO10993-1 included the following tests:
- Cytotoxicity Study Using the ISO Elution Method
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- ISO Systemic Toxicity Study in Mice
- USP Pyrogen Study – Material Mediated
- ASTM Hemolysis Study
- C3a Complement Activation Assay
- SC5b-9 Complement Activation Assay
- In Vivo Thromboresistance Study in the Dog

Sterilization Validation and Packaging
Testing was performed in compliance with ISO11607-1 for Packaging of Sterile devices and ISO11135-1 for Ethylene Oxide Sterilization Validation

The test results demonstrate that the Creganna-Tactx Steerable Sheath Set meets the requirements in the applicable standards and specifications, and is substantially equivalent to legally marketed predicate device.

A GLP Animal study was performed in swine to demonstrate that the device would perform as intended and meet user requirements. Results of this testing demonstrate that the device meets user requirements and meets the intended use of the device.

Clinical studies were not deemed necessary since *in vivo* and *in vitro* testing were sufficient to demonstrate safety and effectiveness by way of comparison to a legally marketed predicate device.

Summary of Substantial Equivalence

Creganna-Tactx Medical believes the Creganna-Tactx Steerable Sheath Set is substantially equivalent to the predicate product. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 1, 2013

Creganna Medical Devices
% Christine Nichols
Regulatory Affairs Manager
Boston Biomedical Associates
386 West Main Street Suite 7
Northborough, MA 01532 US

Re: K131079
Trade/Device Name: Creganna-Tactx™ Steerable Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: July 1, 2013
Received: July 2, 2013

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

510(k) Number (if known): K131079

Device Name: Creganna-Tactx™ Steerable Sheath Set

Indications for Use: The Creganna-Tactx Steerable Sheath Set is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Prescription Use _X_ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S